CLINICAL REQUISITION FORM (HK)

ACT GENOMICS™

All * fields must be filled

PATIENT INFORMATION

* FULL NAME: _____
* HK ID/PASSPORT NO.: _____
ETHNICITY: _____ * GENDER: ☐ Male ☐ Female
* DATE OF BIRTH: (DD/MM/YYYY)_____
* CONTACT NO.: *(WhatsApp ava. For payment)* _____

ORDERING PHYSICIAN INFORMATION

* INSTITUTION NAME: _____
ADDRESS: _____
* PHYSICIAN NAME: _____ CONTACT NO.:_____
* FAX: *(for reporting use)* _____
* EMAIL ADDRESS:*(for reporting use)* _____

DIAGNOSIS AND PATIENT HISTORY

* 1a. DIAGNOSIS OF PRIMARY TUMOUR (MUST CHOOSE ONE)

☐ Breast Carcinoma
ER ☐ +ve ☐ -ve / PR ☐ +ve ☐ -ve / HER2 ☐ +ve ☐ -ve
☐ Colorectal Carcinoma
☐ Ovarian Carcinoma
☐ Lung Cancer
Subtype (if any): ☐ Non-Small Cell Lung Cancer ☐ Adenocarcinoma
☐ Large Cell Carcinoma ☐ Squamous Cell Carcinoma
Please check smoking status
□ Never/Light smoker □ Heavy smoker (>15 pack-years)
☐ Carcinoma of Unknown Primary (CUP)
☐ Other, please specify: _____

*1b. TRANSPLANT INFORMATION (MUST CHOOSE ONE)

☐ Yes ☐ No

2. STAGE OF DISEASE

☐ I ☐ II ☐ III ☐ IV ☐ Other: _____

3. RECEIVED TREATMENT BY LINE *(can select more than one)*

☐ N/A
☐ 1L treatment, receive _____
☐ 2L treatment, receive _____
☐ 3L or above treatment, receive _____

4. PREVIOUS KNOWN MUTATION

☐ Not Tested, ☐ No mutation, ☐ Mutation detected: _____

*TEST SELECTION

*TESTING NAME	DESCRIPTION	TAT (working day)
□ ACTOnco® Pro	DNA+RNA NGS testing: 440 gene mutations, 13 fusion genes, TMB and MSI (□ Back up ACTLiquid Pro)	8
□ PD-L1	IHC 22C3 testing for PD-L1 *(FDA-approved IHC 22C3 pharmDx)*	5
□ MSI Phenotype Assay™	MSI-Markers: *BAT-25, BAT-26, MONO-27, NR-21, NR-24*	10
□ ACTPrecis™ G-U	DNA+RNA NGS testing: *FGFR1-3, IDH1, BRAF, ERBB2, NTRK1-3, UGT1A1*	8
□ ACTPrecis™ GI	DNA+RNA NGS testing: *BRAF, ERBB2, KRAS, NRAS, KIT, PDGFRA, NTRK1-3, UGT1A1*	8
□ ACTNonet™	1st Line hotspots testing: *ALK, ROS1, RET, NTRK1-3, MET, EGFR, KRAS, BRAF, ERBB2* ☐ Bundle with ACTEGFR / ☐ Bundle with ACTEGFR Express	3-5
□ ACTPrecis™ Thorax	DNA+RNA NGS testing at progression: *ALK, ROS1, RET, NTRK1-3, MET (with CNV), EGFR, KRAS, BRAF, ERBB2, NRG1, PIK3CA* ☐ Bundle with ACTEGFR / ☐ Bundle with ACTEGFR Express	8
□ ACTDrug® +	DNA+RNA NGS testing: 40 gene mutations + 13 fusion genes	8
□ ACTFusion®	*13 druggable RNA-based fusion genes*	10
□ ACTHRD™	*BRCA1 & 2* and 22 gene mutations, LGR and HRD score	10
□ ACTHRR™	24 HRR gene mutations, LGR	10
□ ACTBRCA® [Tissue]	*Tissue BRCA1 & 2 mutations, LGR*	10
□ ACTLiquid™ Pro	523 genes mutations, CNV, Fusion TMB and MSI ☐ Bundle with ACTEGFR / ☐ Bundle with ACTEGFR Express	8
□ ACTLiquid™ Lite	54 genes mutations, CNV, Fusion and MSI ☐ Bundle with ACTEGFR / ☐ Bundle with ACTEGFR Express	8
□ ACTEGFR™	*Exon 18 G719X, 19 del, 21 L858R, 21 L861Q, 20 T790M, 20 S768I, 20 insertion*	3
□ ACTEGFR™ Express	*Exon 18 G719X, 19 del, 21 L858R, 21 L861Q, 20 T790M, 20 S768I, 20 insertion*	1
□ ACTMonitor®+	50 gene mutations	10
□ ACTMonitor® Colon	*AKT1, BRAF, CDKN2A, CTNNB1, EGFR, FBXW7, IDH1, IDH2, KRAS, NRAS, PIK3CA, SMAD4, TP53*	10
□ ACTMonitor® Lung	*ALK, BRAF, CDKN2A, CTNNB1, EGFR, ERBB2, KRAS, MET, PIK3CA, TP53, U2AF1*	10
□ ACTMonitor® Breast	*CCND1, CDH1, ERBB2, ESR1, FGFR1, GATA3, PIK3CA, TP53*	10
□ ACTBRCA® [Blood]	*Germline BRCA1 & 2 mutations, LGR*	10
□ ACTCerebra™	40 gene mutations for all solid tumor patients with brain metastasis	8
□ ACTRisk™	*67 hereditary cancer related gene mutations, LGR*	12

*SPECIMEN INFORMATION
(PLEASE PROVIDE COPY OF PATHOLOGY REPORT)

FFPE SPECIMEN SUBMITTING INSTITUTION:

Same as the ordering institution?
☐ Yes ☐ No, please specify:_____

SPECIMEN ID: _____

SPECIMEN SITE (e.g. Right chest wall nodule): _____

COLLECTION DATE(DD/MM/YYYY):_____
a. ☐ Tissue □ Cell Block
b. ☐ Number of specimens: _____ (slides/rolls/blocks)
☐ 1 H&E stain slide

ESTIMATED TUMOUR CONTENT[1]:
☐ 20% ☐ 30% ☐ 50% ☐ 80% ☐ Other: _____%
1 Lowest value in the range would be used if a range of tumour content is provided

SPECIMEN RETURN REQUIREMENT:
☐ Yes ☐ No

LIQUID SPECIMEN SUBMITTING INSTITUTION:
Same as the ordering institution?
☐ Yes ☐ No, please specify:_____

SPECIMEN SITE:
☐ Whole Blood 10mL x 2 in Streck tube *(apply for all, except ACTBRCA® [Blood] & ACTRisk™)*
☐ Whole Blood 4-8mL x 1 in EDTA tube *(ACTBRCA® [Blood] & ACTRisk™ only)*
☐ Pleural Fluid 10mL x 2 in Streck tube *(ACTEGFR only)*
☐ Cerebrospinal Fluid 4-8 mL x 1 in Streck tube *(ACTCerebra™ only)*

COLLECTION DATE(DD/MM/YYYY):_____

Additional document provided to ACT GENOMICS: ☐ Molecular report for FISH/IHC ☐ Copy of pathology reports ☐ Others:_____

*Physician's Declaration: ☐ I declare that the above information provided are accurate.
☐ I declare that the specimen does not contain pathogens or infectious agents such as hepatitis B, hepatitis C, HIV-I or HIV-II.

*ORDERING PHYSICIAN'S SIGNATURE: _____
*SIGNATURE DATE (DD/MM/YYYY): _____

*PATHOLOGY LABORATORY CHOP/SIGNATURE: _____
*SIGNATURE DATE (DD/MM/YYYY): _____

FOR INTERNAL USE ONLY

☐Blood (_____) ☐Pleural Fluid (_____) ☐Slide (_____[H&E:_____]) ☐Other_____ Handled By: _____ Billing: _____
Specimen Arrival Date: _____ Specimen Registration Date: _____

Note: Turnaround Time begins the day samples meet the necessary criteria and arrive at our Taiwan, HK and Thailand laboratory. Taiwan, HK and Thailand Public holidays will be excluded.

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Additional document provided to ACT GENOMICS: ☐ Molecular report for FISH/IHC ☐ Copy of pathology reports ☐ Others:_____

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☐ I declare that the specimen does not contain pathogens or infectious agents such as hepatitis B, hepatitis C, HIV-I or HIV-II.

*ORDERING PHYSICIAN'S SIGNATURE: _____
*SIGNATURE DATE (DD/MM/YYYY): _____

*PATHOLOGY LABORATORY CHOP/SIGNATURE: _____
*SIGNATURE DATE (DD/MM/YYYY): _____

FOR INTERNAL USE ONLY

☐Blood (_____) ☐Pleural Fluid (_____) ☐Slide (_____[H&E:_____]) ☐Other_____ Handled By: _____ Billing: _____
Specimen Arrival Date: _____ Specimen Registration Date: _____

Note: Turnaround Time begins the day samples meet the necessary criteria and arrive at our Taiwan, HK and Thailand laboratory. Taiwan, HK and Thailand Public holidays will be excluded.

基因檢測-受檢者同意書

在您(受檢者)選擇行動基因生技股份有限公司(下稱「行動基因」: 包含香港、台灣、泰國之關聯公司)使用您的檢體進行癌症基因檢測前，希望藉此份說明書讓您能充分了解進行癌症基因檢測的目的、流程、技術侷限及風險，所以請您詳細閱讀此說明書。若您對於此癌症基因檢測還有任何疑問，請在簽名前，再次與您的主診醫生充分討論。

一、檢測目的

行動基因的癌症基因檢測服務，用以偵測特定與癌症相關的基因突變狀況，這些資訊可用於幫助醫生判定癌症的臨床治療,或您可能能夠參與的臨床試驗。

二、檢測流程

經送檢醫生判斷後，您以手術或其他採樣方式所取得之檢體（福馬林固定石蠟包埋檢體、周邊血液或腦脊髓液等）將由行動基因協助安排收件送至行動基因位於香港、台灣台北市或泰國曼谷的實驗室進行檢測。行動基因實驗室於確認檢體符合檢測允收標準後，將依照您與醫生所選擇之檢測服務(如下說明)出具檢測結果，並提供予送檢之醫療機構。

1. 次世代定序檢測服務將利用次世代定序檢測及核酸檢測等技術，針對特定與癌症相關的基因進行定序以得出基因突變數據，之後再透過大型醫藥資料庫進行比對，將所得之定序結果與用藥資訊製作成檢測報告。
2. 微滴式數字聚合酶連鎖反應檢測或免疫染色將針對特定基因進行偵測或染色，並將所得到的檢測結果製作呈檢測報告。

三、檢測技術的侷限與風險

1. 若檢體符合允收標準，將進行完整之檢測流程，並依檢體質量提供檢測結果；若檢測過程未達品質監控標準，將由送檢醫生共同評估重新採取檢體或終止檢測。
2. 次世代定序檢測、微滴式數字聚合酶連鎖反應檢測或免疫染色及其他檢測等技術仍有其限制，該檢測準確率並非百分之百。
3. 檢測範圍以基因突變為主，由於檢測技術限制以及個別檢體腫瘤基因差異等原因，即使檢測人員已確實執行標準操作程序，仍可能在所檢測之特定基因上未發現任何突變異常，或可能導致部分檢測結果無法提供之情形，例如：拷貝數變異(CNV)、微小衛星體不穩定性(MSI)、腫瘤突變負荷量(TMB)等。
4. 檢測結果所發現的突變狀況在目前的醫藥資料庫中可能 a.尚無相對應藥物 b.尚處於臨床測試階段 c.與您目前或曾經接受的治療藥物相同。

四、檢測報告及檢體說明

1. 癌症基因變異與治療結果的相關資訊隨著醫學研究持續改變，您的醫療團隊將整合臨床資料，例如:血液及影像數據，可能對於檢測結果所比對的藥物有不同意見。檢測結果僅供專業醫療人員參考，不代替專業醫療人員的獨立專業醫療判斷，且不得被視為對任何人提供診斷或醫學治療建議。
2. 礙於醫學專有名詞及文獻查證之需求，檢測報告以英文呈現，以便醫療機構作為參考。
3. 您若須取得紙本報告，依據規範須於委託之醫療機構進行申請，以保障您的安全。
4. 基因檢測有可能偵測出與遺傳相關訊息，針對任何檢測結果的臨床上解讀，請諮詢醫師協助您評估後續健康管理之注意事項。
5. 行動基因將留存檢測結果 7 年或依相關法規要求留存更久的期間，用於提供服務予您或與開立醫囑之送檢醫生討論。
6. 檢測後如有剩餘檢體，行動基因將於檢測報告完成後 6 個月內，於法律允許的範圍內將剩餘檢體以去連結化的方式移除信息後，留存剩餘檢體並進行醫學分析使用。但若您於次頁「受檢者聲明」中勾選**不同意**，行動基因將銷毀剩餘檢體。

您的隱私以及個人信息都會依照相關法律予以保密

受檢者聲明：

- 本人/代理人已與開立醫囑的醫生討論，願意執行檢測並承擔檢測相關風險。本人同意由送檢之醫療機構提供本人醫療資訊予行動基因，如:檢體、病理報告及用藥紀錄等，以利檢測之進行及報告之分析運用。本人亦了解行動基因會依相關法規將檢測結果提供予以下填寫之轉介之醫療機構：

  轉介醫療機構：_____（醫院/診所）

  送檢醫生：_____ 檢測項目(如ACTOnco® Pro)：_____

- 本人已詳細閱讀及充分了解本基因檢測受檢者同意書(本「同意書」)所載之內容，**本人對本同意書所載之內容茲此表示同意**，並同意行動基因得依據本同意書內容蒐集、處理、利用本人之個人資料。
- **本人已知悉需完成付款後行動基因才開始進行基因檢測**。

受檢者非必填項目：

下列事項本人未勾選，或將同意與不同意兩項同時勾選者，則視為不同意。

□同意□不同意	生技製藥公司研發與本人檢測結果有關之新藥/治療方法時，行動基因得將送檢醫生資訊提供予生技製藥公司，由送檢醫生判斷該新藥/治療方法是否有助於本人未來治療。
□同意□不同意	在符合個人資料保護法及相關法規前提下，行動基因於去除基因資訊及檢測結果中可直接或間接識別本人身分之資訊後，可運用該些去連結後之資料，例如:建立資料庫或提供其他機構、公司查詢或研究之用。
□同意□不同意	行動基因可將本人預後(Prognosis)追蹤資訊，進行醫學研究分析使用。
□同意□不同意	行動基因可在法律允許的範圍內，將本人之剩餘檢體以去連結的方式留存並進行醫學研究分析使用。

立同意書人(受檢者)

受檢者姓名：_____ 身分證/護照號碼：_____

受檢者生日：_____年_____月_____日 聯絡電話：_____

家屬聯絡人電話：_____ 與受檢者之關係：_____

通訊地址：_____

受檢者/代理人簽名：_____ 與受檢者之關係：_____

簽署日期 ： _____年_____月_____日